UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION THIS DOCUMENT RELATES TO: The City of New York v. Abbott Labs., et al. (S.D.N.Y. No. 04-CV-6054) County of Albany v. Abbott Labs., et al. (N.D.N.Y. No. 05-CV-0425) County of Allegany v. Abbott Labs., et al. (W.D.N.Y. No. 05-CV-0236) County of Broome v. Abbott Labs., et al. (N.D.N.Y. No. 05-CV-0456) County of Cattaraugus v. Abbott Labs., et al.) (W.D.N.Y. No. 05-CV-0256) County of Cayuga v. Abbott Labs., et al. (N.D.N.Y. No. 05-CV-0423) County of Chautauqua v. Abbott Labs., et al.) (W.D.N.Y. No. 05-CV-0214) County of Chenango v. Abbott Labs., et al. (N.D.N.Y. No. 05-CV-0354) County of Chemung v. Abbott Labs., et al. (W.D.N.Y. No. 05-CV-6744) County of Columbia v. Abbott Labs., et al. (N.D.N.Y. No. 05-CV-0867) County of Cortland v. Abbott Labs., et al. (N.D.N.Y. No. 05-CV-0881) County of Dutchess v. Abbott Labs., et al. (S.D.N.Y. No. 05-CV-6458) County of Essex v. Abbott Labs., et al. (N.D.N.Y. No. 05-CV-0878) County of Fulton v. Abbott Labs., et al. (N.D.N.Y. No. 05-CV-0519) County of Genesee v. Abbott Labs., et al. (W.D.N.Y. No. 05-CV-0267) County of Greene v. Abbott Labs., et al. (N.D.N.Y. No. 05-CV-0474) County of Herkimer v. Abbott Labs., et al. (N.D.N.Y. No. 05-CV-0415)

MDL No. 1456 Civil Action No. 01-12257-PBS

Judge Patti B. Saris

THE ROCHE DEFENDANTS'
SUPPLEMENTAL MEMORANDUM
OF LAW IN SUPPORT OF MOTIONS
TO DISMISS (1) THE CONSOLIDATED
COMPLAINT OF NEW YORK CITY
AND PLAINTIFF NEW YORK
COUNTIES OTHER THAN NASSAU
AND (2) THE SECOND AMENDED
COMPLAINT OF NASSAU COUNTY

County of Jefferson v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-0715))
County of Lewis v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-0839))
County of Madison v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-0714))
County of Monroe v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-6148))
County of Niagara v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-6296)	ĺ,
County of Oneida v. Abbott Labs., et al	ĺ
(N.D.N.Y. No. 05-CV-0489)	í
County of Onondaga v. Abbott Labs., et al.	í
(N.D.N.Y. No. 05-CV-0088)	í
County of Ontario v. Abbott Labs., et al.	ĺ
(W.D.N.Y. No. 05-CV-6373)	í
County of Orleans v. Abbott Labs., et al.	í
(W.D.N.Y. No. 05-CV-6371)	í
County of Putnam v. Abbott Labs., et al.	í
(S.D.N.Y. No. 05-CV-4748)	í
County of Rensselaer v. Abbott Labs., et al.	í
(N.D.N.Y. No. 05-CV-0422)	á
County of Rockland v. Abbott Labs., et al.	í
(S.D.N.Y. No. 03-CV-7055)	í
County of St. Lawrence v. Abbott Labs., et al.	ĺ.)
(N.D.N.Y. No. 05-CV-0479)	ĺ
County of Saratoga v. Abbott Labs., et al.	í
(N.D.N.Y. No. 05-CV-0478)	ĺ,
County of Schuyler v. Abbott Labs., et al.	í
(W.D.N.Y. No. 05-CV-6387)	í
County of Seneca v. Abbott Labs., et al.	ĺ
(W.D.N.Y. No. 05-CV-6370))
County of Steuben v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-6223))
County of Suffolk v. Abbott Labs., et al.)
(E.D.N.Y. No. CV-03-0229))
County of Tompkins v. Abbott Labs. et al.)
(N.D.N.Y. No. 05-CV-0397))
County of Warren v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-0468))
County of Washington v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-0408))
County of Wayne v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-6138))
County of Westchester v. Abbott Labs., et al.)
(S.D.N.Y. No. 03-CV-6178))

County of Yates v. Abbott Labs., et al. (W.D.N.Y. 05-CV-6172)	;
County of Nassau v. Abbott Labs., et al. (E.D.N.Y. No. 04-CV-5126)	;

Despite more than ample opportunity over the last three years to draft complaints that comply with this Court's repeated guidance, the plaintiffs in these actions have failed to state any cognizable claim against Hoffmann-La Roche Inc. and Roche Laboratories Inc. (together, "Roche"). Indeed, this Court dismissed Roche from the Amended Master Consolidated Class Action Complaint ("AMCC") in this MDL because of similarly vague and conclusory pleadings. The allegations in the Consolidated Complaint ("Cons. Comp.") and the County of Nassau's Second Amended Complaint ("Nassau SAC") are entirely inadequate, and plaintiffs' claims against Roche should be dismissed with prejudice pursuant to Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure.

BACKGROUND

In its opinion dated February 24, 2004, this Court dismissed Roche from the AMCC, noting, among other things, that:

The Court dismisses Hoffmann-La Roche on the ground that there are insufficient allegations to support a claim of a fraudulent scheme. While industry-wide practices are relevant, this is essentially a guilt-by-association claim as there are no allegations concerning government investigations, internal documents, or specific fraudulent spreads relating to this particular company.... Plaintiffs further argue that under First Circuit precedent, the proper course is to permit discovery, noting that unlike the other Defendants, Hoffmann-La Roche has never been subject to discovery.... Here, the Court makes the [] determination that discovery is not warranted....no specifics have been alleged as to the conduct of Hoffmann-La Roche. Therefore, Hoffmann-La Roche's motion to dismiss is ALLOWED.

In re Pharm. Industry Avg. Wholesale Price Litig., 307 F. Supp. 2d 196, 209-10 (D. Mass. 2004).

¹ In addition to the arguments made herein, Roche fully adopts and incorporates by reference the arguments set forth in Defendants' Joint Memorandum of Law in Support of Motions to Dismiss (1) The Consolidated Complaint of New York City and Plaintiff New York Counties Other Than Nassau and (2) The Second Amended Complaint of Nassau County.

As discussed more fully in Defendants' Joint Memorandum, the *County of Suffolk* case — the opening salvo in the New York counties' AWP suits — was originally filed by the firm of Kirby McInerney & Squire on January 14, 2003. Roche was not named as a defendant in the *Suffolk* action. Motions to dismiss the *Suffolk* complaint were partially granted. The Kirby firm filed the Consolidated Complaint on June 15, 2005 — more than two years later — with the benefit of this Court's decisions regarding the AMCC, the *Suffolk* case, and other related cases. Plaintiff Nassau County filed its original complaint on November 24, 2004 and its current complaint, the Nassau SAC, on January 6, 2006.² The Nassau SAC is nearly identical to the Consolidated Complaint, except that it has kept the RICO claim previously dismissed by this Court in *Suffolk*.

Plaintiffs devote only a few paragraphs to Roche out of their two-hundred-page complaints. None of these paragraphs pleads any facts that, if proven, would support a cause of action against Roche. As to Roche, plaintiffs' Complaints only: (i) identify the two Roche defendants³ (Cons. Comp. ¶ 66, Nassau SAC ¶ 43); (ii) set forth the amounts allegedly spent by the counties in Medicaid payments for Roche's products from 1997-2003 (Cons. Comp. ¶ 523, Nassau SAC ¶ 433), and a list of those products and their AWPs; (iii) conclusorily allege that Roche set fraudulent AWPs for its products, marketed the spread, and failed to report Best Price, with only two products noted (Cons. Comp. ¶¶ 524-27, Exh. A; Nassau SAC ¶¶ 433-36, Exh. B); (iv) refer to Congressional investigations; and (v) make a throwaway allegation that Roche has been sued by the State of Alabama (Cons. Comp. Exh. D). Notably, the Consolidated Complaint does *not* include any Roche products in its charts of AWPs and "spreads" in Exhibits B and F.

² Although counsel for Nassau reported in their initial motion for leave to amend that no new defendants would be added to the Nassau SAC, Roche was named for the first time in the SAC.

³ The Consolidated Complaint also specifies that Roche is one of the subgroup of new defendants against which the County of Suffolk now asserts claims. (Cons. Comp. ¶ 32).

Nassau adds the vague allegation that Roche participated in a "Manufacturer-Publisher enterprise" under RICO (Nassau SAC ¶ 437), but also does *not* include any Roche products in its chart of "Fraudulent AWP" and "Spread" in its Exhibit A.

In an effort to create an appearance of wrongdoing on Roche's part, plaintiffs allege that Roche -- like many pharmaceutical companies -- received inquiries years ago from the House Committee on Energy and Commerce and the Senate Finance Committee (Cons. Comp. ¶¶ 156 n.10, 159 n.11, 528-29; Nassau SAC ¶¶ 161 n.5, 167 n.6, 438-39). That Congress sent a letter to a number of companies, does not, however, mean that Roche was "investigated." Indeed, this Court has recognized that the mere fact of an investigation does not, in and of itself, create an inference of improper conduct. Trans. of Apr. 8, 2005 Hr'g, at 20. *Accord Gotlin v. Lederman*, 367 F. Supp. 2d 349, 363 (E.D.N.Y. 2005) (noting that "references in pleadings to administrative investigations that do not result in adjudication of underlying issues are immaterial and can properly be stricken") (citations omitted).

These general allegations of Congressional inquiries cannot salvage plaintiffs' pleading deficiencies. Plaintiffs do not -- because they cannot -- state that any Congressional committee, or any other governmental authority, has concluded or stated that Roche engaged in any wrongful activity regarding its pharmaceutical pricing. Roche did not provide any Congressional testimony, and was not the subject of any findings. The House investigation cited by plaintiffs ended in December 2004 without any finding that Roche had undertaken improper activity. See Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much: Hearing Before the Subcomm. on Oversight & Investigations of the Comm. on Energy & Commerce, 108th Cong. 126 (2004), at 2 ("Today's hearing, which is a culmination of an extensive investigation..."). This Court can take judicial notice of this, since it is a matter of public record.

Greene v. Rhode Island, 398 F.3d 45, 48 (1st Cir. 2005). Moreover, the Finance Committee inquiry does not even relate to AWP, but rather concerns transactions made at nominal prices. Plaintiffs' baseless invocation of "investigations" is not sufficient to draw Roche into this litigation.

Similarly, plaintiffs' "spread" allegations against Roche products are nothing more than empty incantations with not a single fact alleged to support the conclusion. While plaintiffs purport to allege AWP/"market price" "spreads" for two Roche products (Cons. Comp. ¶¶ 526-27, Nassau SAC ¶ 440), these isolated data points -- alleged for only one reporting period in the many years at issue in this case-- do not reflect an allegedly fraudulent course of conduct.

Moreover, plaintiffs have never supported their source for the alleged "market prices," and the prices Nassau alleges for Roche's Klonopin are entirely different from the Consolidated Complaint's Klonopin prices, but are identical to the Consolidated Complaint's Kytril prices.

ARGUMENT

I. Plaintiffs Have Not Sufficiently Alleged "Investigations," Internal Documents, or Fraudulent Spreads.

Plaintiffs' vague and cursory allegations are inadequate to support their claims for relief against Roche. Therefore, Roche requests that this Court grant its motion to dismiss under Federal Rules of Civil Procedure 12(b)(6) and 9(b). See In re Colonial Mortgage Bankers Corp., 324 F.3d 12, 15 (1st Cir. 2003) (court, in considering 12(b)(6) motion, assumes truth of all well-pleaded facts but need not credit "bald assertions [or] unsupportable conclusions") (internal punctuation and citation omitted). As discussed above, this Court has held that in order to survive a motion to dismiss in this MDL, plaintiffs must properly allege "government investigations, internal documents, or specific fraudulent spreads." In re Pharm. Industry Avg. Wholesale Price Litig., 307 F. Supp. 2d at 209; accord U.S. ex rel. Karvelas v. Melrose-

Wakefield Hosp., 360 F.3d 220, 226 (1st Cir. 2004) (holding plaintiff must specify "time, place, and content of the alleged false or fraudulent representations"). As noted above, after years of investigations by private plaintiffs and governmental authorities, plaintiffs have failed to allege any internal documents, government investigations, or spreads that could reasonably result in an inference of fraud on Roche's part. Plaintiffs do not even include a single Roche product on their charts of "Fraudulent AWPs." Just as it does not suffice to claim that a defendant is a pharmaceutical manufacturer and thus subject to liability in this case, plaintiffs cannot drag Roche into this litigation merely by reciting the magic words "investigation" and "spread." Consistent with this Court's prior opinions, plaintiffs' claims against Roche should be dismissed. See In re Pharm. Industry Avg. Wholesale Price Litig., 307 F. Supp. 2d at 209; County of Suffolk v. Abbott Labs., Inc., 2004 WL 2387125, at *2 (D. Mass. Oct. 26, 2004).

II. Plaintiffs' Complaint Is Facially Deficient As To Roche In Several Other Respects.

As more fully set forth in defendants' joint brief, plaintiffs' claims are facially deficient as to Roche in the following respects:

- The Nassau SAC includes a skeletal allegation that Roche engaged in a RICO enterprise with publishers. Like the RICO claims that this Court has dismissed twice in the AWP litigation, *In re Pharm. Industry Avg. Wholesale Price Litig.*, 307 F. Supp. 2d at 204; *County of Suffolk v. Abbott Labs.*, 339 F. Supp. 2d 165, 175 (D. Mass. 2004), Nassau's allegations are inadequate to support its RICO claim against Roche.
- Plaintiffs' use of AWP in determining spread is also at odds with their allegations that WAC, not AWP, is the fraudulent price at issue (Cons. Comp. ¶¶ 7-8, Nassau SAC ¶ 6).
- In addition, Plaintiffs fail to explain how Roche's physician-administered drugs (such as the Kytril dosage referenced in ¶ 527 of the Consolidated Complaint) could be subject to pricing fraud. As this Court noted in its first *Suffolk* decision, New York Medicaid requires physician-administered drugs to be "billed by the physician at the 'actual cost of the drugs to practitioners.'" *County of Suffolk*, 339 F. Supp. 2d at 174 (citing N.Y. Soc. Serv. L. § 367-a(9)(a)). Plaintiffs do not explain how, given this mandate, Roche could have possibly executed any pricing fraud with regard to physician-administered drugs.

For the above reasons, as well as those set forth in Defendants' Joint Memorandum,

Plaintiffs' claims against Roche should be dismissed.

March 3, 2006

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